

Message

From: Owens, Beth [Owens.Beth@epa.gov]
Sent: 11/12/2020 4:00:37 PM
To: Jones, Samantha [Jones.Samantha@epa.gov]
CC: Lambert, Jason [Lambert.Jason@epa.gov]
Subject: RE: PFBS - LATE COMMENTS FROM OPPT

Will do.

From: Jones, Samantha <Jones.Samantha@epa.gov>
Sent: Thursday, November 12, 2020 11:00 AM
To: Owens, Beth <Owens.Beth@epa.gov>
Cc: Lambert, Jason <Lambert.Jason@epa.gov>
Subject: Re: PFBS - LATE COMMENTS FROM OPPT

The invite was just canceled k Ex. 5 Deliberative Process (DP)

So, if you don't mind, Beth, could you send a note to Wayne, Kay, and Kelly?

Sent from my iPhone

On Nov 12, 2020, at 10:58 AM, Owens, Beth <Owens.Beth@epa.gov> wrote:

Did you already inform Wayne, Kelly or should I mention it?

From: Jones, Samantha <Jones.Samantha@epa.gov>
Sent: Thursday, November 12, 2020 10:36 AM
To: Owens, Beth <Owens.Beth@epa.gov>
Cc: Lambert, Jason <Lambert.Jason@epa.gov>
Subject: Re: PFBS - LATE COMMENTS FROM OPPT

Ex. 5 Deliberative Process (DP) I have a feeling we will have to meet with OPPT.

Sent from my iPhone

On Nov 12, 2020, at 10:27 AM, Jones, Samantha <Jones.Samantha@epa.gov> wrote:

Ok, got a text from Lou...no PFBS today; Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) The briefing will likely stay on the calendar because they want to talk GAO and Iris. You wouldn't need to attend.

Hoping to get more info....

Ex. 6 Personal Privacy (PP)

Sent from my iPhone

On Nov 12, 2020, at 9:32 AM, Owens, Beth <Owens.Beth@epa.gov> wrote:

Ok, we'll stay on the ready.

From: Jones, Samantha <Jones.Samantha@epa.gov>
Sent: Thursday, November 12, 2020 9:32 AM
To: Owens, Beth <Owens.Beth@epa.gov>
Cc: Lambert, Jason <Lambert.Jason@epa.gov>
Subject: Re: PFBS - LATE COMMENTS FROM OPPT

Not sure about briefing. I believe DDD wants to reschedule and JOZ wants to keep. I am checking email periodically to see if there's any word. ☹️

Sent from my iPhone

On Nov 12, 2020, at 9:06 AM, Owens, Beth <Owens.Beth@epa.gov> wrote:

Are we thinking there might still be the briefing today?
And agree, awesome email. Thank you!

From: Jones, Samantha <Jones.Samantha@epa.gov>
Sent: Thursday, November 12, 2020 8:41 AM
To: Lambert, Jason <Lambert.Jason@epa.gov>
Cc: Owens, Beth <Owens.Beth@epa.gov>
Subject: Re: PFBS - LATE COMMENTS FROM OPPT

Thanks Jason!! That is excellent to hear, Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

JOZ wrote back but I'm unclear on our path for today.
I'll forward her response.

Sent from my iPhone

On Nov 12, 2020, at 8:20 AM, Lambert, Jason <Lambert.Jason@epa.gov> wrote:

Samantha,
Bravo on the email back to JOZ et al.
yesterday! I just read carefully the Ex. 5
memo provided by OPPT. Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Jason C. Lambert, PhD, DABT
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and Exposure
U.S. Environmental Protection Agency
26 West Martin Luther King Dr.
Cincinnati, OH 45268
(513)-569-7078
lambert.jason@epa.gov

From: Jones, Samantha
<Jones.Samantha@epa.gov>
Sent: Wednesday, November 11, 2020
1:20 PM
To: Lambert, Jason
<Lambert.Jason@epa.gov>; Owens,
Beth <Owens.Beth@epa.gov>
Subject: FW: PFBS - LATE COMMENTS
FROM OPPT
Importance: High

Please see attachment and my initial
response to Jennifer below. If I've
misrepresented anything below, please
let me know.

Sorry!!!

Samantha

From: Jones, Samantha
Sent: Wednesday, November 11, 2020
1:18 PM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Thayer,
Kris <thayer.kris@epa.gov>; Cascio,
Wayne <Cascio.Wayne@epa.gov>
Cc: D'Amico, Louis
<DAmico.Louis@epa.gov>
Subject: RE: PFBS

Hi Jennifer,

I am concerned with these last minute comments from OPPT considering the following:

OVERARCHING: OPPT commented on the draft PFBS assessment during the final Agency and Interagency review stage prior to us sending the revised assessment to IOAA for final clearance. These comments were not raised during that time (or in previous reviews).

Additionally, prior to this, when the assessment was revised after public comment and it was decided that we would go for another round of external peer review, the charge questions, highlighting the BMR as well as the uncertainty factors, were circulated for review by the Agency and Interagency reviewers (late Dec 2019/early Jan 2020). No comments or recommendations were received at that time on these two topics. We subsequently underwent a second external peer review with agreement with the decisions presented in the latest version of the assessment.

REGARDING THE BENCHMARK RESPONSE (BMR): A 20% BMR was used in earlier drafts of the assessment for the thyroid hormone changes; however, based on comments from the public raising some questions around the confidence in the 20% BMR and the recommendation to use the standard deviation approach statistically recommended for continuous data (like thyroid hormone changes), we adjusted the PFBS assessment, went through agency and interagency review of the charge questions (as noted above) and then a second round of external peer review, as well as final agency and interagency review, all with agreement on this approach. It would have been helpful to hear more about the Endocrine Disruptor Screening Program statement regarding a 20% BMR that seems to be viewed as guidance in the comments during the multiple engagements within the Agency.

REGARDING THE DATABASE UF: OPPT
was asked to comment on PFBS
assessment to provide perspective on
whether OPPT would apply such
uncertainty factors within OPPT under
the Toxic Substances Control Act
(TSCA). OPPT disagreed with the
application of the database UF but it is
unclear why they would weigh in on this
since it isn't considered or applied in the
TSCA chemical risk evaluations.

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP) ORD routinely considers the
evidence base for a chemical and
whether to apply a quantitative value for
the database uncertainty factor in all of
its assessments that develop reference
values. The application in PFBS is
consistent with practices in those
assessments and has been rigorously
reviewed by agency (including OPPT),
interagency, and external peer
reviewers. To change now would
undermine those previous processes.

I am forwarding these comments to the
team so that we can dig in further
especially regarding the dismissal of the
3-fold application of a database UF for
the absence of a developmental
neurotoxicity. I don't agree with the
outright dismissal noted by OPPT but
would like to confer with the assessment
leads and discuss the PFBS evidence
base and considerations in light of these
comments.

I'll note that it is unlikely that they will
see this email since today is a holiday
and they will not be checking email.

Thanks,
Samantha

Samantha J. Jones, PhD
Associate Director, Center for Public Health
and Environmental Assessment (CPHEA)
National Program Director, Health and
Environmental Risk Assessment (HERA)
Research Program
Office of Research and Development (ORD)
US Environmental Protection Agency (EPA)
RRB 71210, Washington, DC
(o) 202-564-6794; (m) Ex. 6 Personal Privacy (PP)

From: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Sent: Wednesday, November 11, 2020 11:45 AM
To: Jones, Samantha <Jones.Samantha@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>
Cc: D'Amico, Louis <DAmico.Louis@epa.gov>
Subject: FW: PFBS

See attached and let me know asap
whats up here. I thought they had
previously signed off

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant
Administrator
Office of Research and Development
US Environmental Protection Agency

DC
Ce

Ex. 6 Personal Privacy (PP)

From: Dunlap, David
<dunlap.david@epa.gov>
Sent: Wednesday, November 11, 2020 11:33 AM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Cc: D'Amico, Louis <DAmico.Louis@epa.gov>
Subject: FW: PFBS

Jennifer,

As you and I are aware, OPPT reviewed the draft GenX assessment and provided some recent comments to OW (as they are the lead on the GenX assessment). I had distributed those GenX comments to ORD's PFBS team for awareness. It seems, in light of those GenX concerns, OPPT decided to review and comment on the PFBS assessment. See attached.

Not exactly sure how these concerns can be resolved, but I do know that our first real discussion about these concerns should not occur in front of

the Administrator. So I suggest two immediate actions:

- Postpone Thursday's PFBS discussion with the Administrator (we can still meet and review the GAO draft response), and
- Set up a meeting with OCSPP to discuss their PFBS concerns and a potential resolution.

Thoughts?

DDD

David D. Dunlap
O – 202.564.6620

From: Fischer, David
<Fischer.David@epa.gov>
Sent: Tuesday, November 10, 2020
11:34 AM
To: Hoverman, Taylor
<hoverman.taylor@epa.gov>; Dunlap, David <dunlap.david@epa.gov>;
Bertrand, Charlotte
<Bertrand.Charlotte@epa.gov>; Ross, David P <ross.davidp@epa.gov>
Subject: RE: PFBS

All, OPPT developed the appended document on UFs for PFBS; as you will see, OPPT would have used a different UF value for data insufficiency. Thanks.

David

David B. Fischer, M.P.H., J.D.
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